

NTP Historical Controls Report

By Route and Vehicle

Wistar-Han RATS

August 2016

REPORT DESCRIPTION

This report shows the tumor rates of control group animals from selected studies. The studies used are shown on the Study Summary page.

This report is broken up into sections based on the route and vehicle used to deliver the chemical. The Table of Contents on Page 3 shows the different Route/Vehicle combinations. To see the data from all routes and vehicles combined into one set, you must run the "All Routes" report.

The individual tumor rates shown on the data pages of the report relate to the Study Summary page as follows: the tumor rates are shown in the same order as the Study Summary page, except that they are grouped horizontally in sets of three, with the males in the first set of three and the females in the second set. For example if the study summary showed the studies like this:

Male
M1
M2
M3
M4
M5
Female
Female F1
F1
F1 F2

the data would be shown as:

	Male		Female					
M1	M2	M3	F1	F2	F3			
M4	M5		F4	F5				

Directly beneath the individual tumor rates on the data pages are the overall totals for that tumor/site combination. This includes the total tumors/animals, the overall mean (in parentheses), the mean of the study means, and the standard deviation of the study means.

Studies with no control animals of a particular gender are listed on the summary page with the Number of Animals shown as zero and the Start Date and Length of Study shown as "N/A". On the data pages there are blank spaces where tumor rates for these studies would normally be found, so that the male and female rates for the remaining studies can be easily compared.

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Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Toxicology Data Management System

Page: 4

Report Date: 08/04/2016

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Southern Research Institute	052020903	08/26/08	729	49(3)	36(671)	673.4	Pentabromodiphenyl Ether Mixture [DE-71 (Technical Grade)]
Battelle Columbus Laboratory	052032003	07/25/07	727	50(3)	33(642)	662.9	Tetrabromobisphenol A
					Female		
Southern Research Institute	052020903	08/26/08	732	50(5)	37(678)	389.6	Pentabromodiphenyl Ether Mixture [DE-71 (Technical Grade)]
Battelle Columbus Laboratory	052032003	07/26/07	728	50(5)	34(678)	375.2	Tetrabromobisphenol A

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: Wistar-Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 5

			Male				Female	
#All Organs: Benign Tumors								
		33/49 (67%)	30/50 (60%)			37/50 (74%)	38/50 (76%)	
Overall Incidence	Total	63/99 (63.64%)	Mean 63.67%	SD 5.2%	Total	75/100 (75%)	Mean 75%	SD 1.41%
#All Organs: Malignant Tumors								
		13/49 (27%)	8/50 (16%)			10/50 (20%)	10/50 (20%)	
Overall Incidence	Total	21/99 (21.21%)	Mean 21.27%	SD 7.45%	Total	20/100 (20%)	Mean 20%	SD 0%
#All Organs: Malignant and Benign Tu	umors	36/49 (73%)	34/50 (68%)			40/50 (80%)	40/50 (80%)	
Overall Incidence	Total	70/99 (70.71%)	Mean 70.73%	SD 3.87%	Total	80/100 (80%)	Mean 80%	SD 0%
#All Organs: Hemangioma Overall Incidence	Total	1/49 (2%) 2/99 (2.02%)	1/50 (2%) Mean 2.02%	SD 0.03%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Overall incidence		2/99 (2.02%)			·····			3D 0%
#All Organs: Hemangiosarcoma								
		8/49 (16%)	3/50 (6%)			2/50 (4%)	2/50 (4%)	
Overall Incidence	Total	11/99 (11.11%)	Mean 11.16%	SD 7.3%	Total	4/100 (4%)	Mean 4%	SD 0%
#All Organs: Hemangiosarcoma or He	emangioma							
		9/49 (18%)	4/50 (8%)			2/50 (4%)	2/50 (4%)	
Overall Incidence	Total	13/99 (13.13%)	Mean 13.18%	SD 7.33%	Total	4/100 (4%)	Mean 4%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 6

			Male				Female	
#All Organs: Histiocytic Sarcoma								
-		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Leukemia: Lymphocytic,	Monocytic, M	ononuclear, or Undifferer	ntiated					
		1/49 (2%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/99 (2.02%)	Mean 2.02%	SD 0.03%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Malignant Lymphoma: His Overall Incidence	stiocytic, Lym Total	phocytic, Mixed, NOS, or 0/49 (0%) 0/99 (0%)	Undifferentiated Cel 0/50 (0%) Mean 0%	I Type SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#All Organs: Mesothelioma: Benign, M	alignant, NOS	3 0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Mesothelioma: Malignant						0/50 (09/)	0/50 /00/	
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#All Organs: Osteoma		0/40 (0%)	0/50 (09/)			0/50 (09/)	0/50 (09/)	
Overell Incidence	Total	0/49 (0%)	0/50 (0%)	CD 00/	Total	0/50 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: Wistar-Han

Species: RATS

Toxicology Data Management System

Page: 7

Report Date: 08/04/2016

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
#All Organs: Osteosarcoma								
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
				30 0/0				
#All Organs: Osteosarcoma or Osteoma								
		0/49 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Adrenal Cortex: Adenoma								
		0/49 (0%)	0/50 (0%)			1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 0%
*Adrenal Cortex: Carcinoma								
		1/49 (2%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Adrenal Medulla: Pheochromocytoma Benign	ı							
		0/49 (0%)	0/49 (0%)			1/50 (2%)	2/49 (4%)	
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	3/99 (3.03%)	Mean 3.04%	SD 1.47%
*Adrenal Medulla: Pheochromocytoma Comple	ех							
		0/49 (0%)	0/49 (0%)	25 22/		1/50 (2%)	0/49 (0%)	25
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	1/99 (1.01%)	Mean 1%	SD 1.41%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 8

			Male				Female					
*Adrenal Medulla: Pheochromocytoma Malignant												
		1/49 (2%)	0/49 (0%)			0/50 (0%)	0/49 (0%)					
Overall Incidence	Total	1/98 (1.02%)	Mean 1.02%	SD 1.44%	Total	0/99 (0%)	Mean 0%	SD 0%				
*Adrenal Medulla: Pheochromocytoma: Be												
	3 ,	1/49 (2%)	0/49 (0%)			2/50 (4%)	2/49 (4%)					
Overall Incidence	Total	1/98 (1.02%)	Mean 1.02%	SD 1.44%	Total	4/99 (4.04%)	Mean 4.04%	SD 0.06%				
#Blood Vessel: Hemangiosarcoma												
	-	0/49 (0%)	1/50 (2%)	00 4 440/		0/50 (0%)	0/50 (0%)	00.00/				
Overall Incidence	Total	1/99 (1.01%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Bone Marrow: Hemangiosarcoma		0/40 /00/)	0/50 /00/			0/50 /00/)	0/50 (00/)					
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Bone: Osteoma												
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Bone: Osteosarcoma	•••••											
		0/49 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)					
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page**: 9

			Male				Female	
#Bone: Osteosarcoma or Osteoma								
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
				30 0/6	10tai			
#Bone: Sarcoma								
		0/49 (0%)	0/50 (0%)	05 00/		0/50 (0%)	0/50 (0%)	OD 201
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Glioma								
Occupation of James	T-1-1	0/49 (0%)	0/50 (0%)	OD 00/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Glioma Malignant		4/40 (004)	0/50 (00/)			0(50 (00))	0/50 (00/)	
Overall Incidence	Total	1/49 (2%) 1/99 (1.01%)	0/50 (0%) Mean 1.02%	SD 1.44%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Granular Cell Tumor Benign								
		1/49 (2%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/99 (2.02%)	Mean 2.02%	SD 0.03%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Granular Cell Tumor Maligna	ant							
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 10

			Male				Female	
*Brain: Meningioma Malignant								
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Meningioma: Benign, Malig	ınant, NOS							
3 3 4 3 7 4 3	,,	0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma Benign		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma, Glioma		rtoma						
Overall Incidence	Total	1/49 (2%) 1/99 (1.01%)	0/50 (0%) Mean 1.02%	SD 1.44%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma								
		1/49 (2%)	0/50 (0%)	05		0/49 (0%)	0/50 (0%)	05 00/
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	0/99 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma or Adenoma		4/40 /00/	0/50 /00/			0/40 (00%)	0/50 /00/	
Overall Incidence	Total	1/49 (2%) 1/99 (1.01%)	0/50 (0%) Mean 1.02%	SD 1.44%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
Overall incluence	ı Olai	, ,				0/99 (0%)		3D 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 11

			Male				Female	
*Heart: Schwannoma Benign		0/10 (05)	0/50 (00.1)			0/50 (000)	4/50 (00/)	
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
*Heart: Schwannoma NOS								
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Duodenum: Fibroma								
Overall Incidence	Total	1/49 (2%) 1/99 (1.01%)	0/50 (0%) Mean 1.02%	SD 1.44%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Duodenum: Leiomyosarcoma						0/50 /00/\	4/50 (20/)	
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
#Intestine Small: Jejunum: Leiomyoma			•••••					
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma								
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: Wistar-Han

Species: RATS

Toxicology Data Management System

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Report Date: 08/04/2016

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
#Intestine Small: Site Unspe Fibroma	ecified:							
		1/49 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspe Leiomyoma	ecified:							
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspe Leiomyosarcoma								
		0/49 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Islets, Pancreatic: Adenoma								
		4/49 (8%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	5/99 (5.05%)	Mean 5.08%	SD 4.36%	Total	0/100 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Carcinoma								
		2/49 (4%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/99 (2.02%)	Mean 2.04%	SD 2.89%	Total	0/100 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Carcinoma or Adenoma								
		6/49 (12%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	7/99 (7.07%)	Mean 7.12%	SD 7.24%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 13

			Male				Female					
*Kidney: Pelvis and Transitional Epithelium: Papilloma												
		0/49 (0%)	0/50 (0%)	05 00/		0/50 (0%)	0/50 (0%)	00.00				
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Kidney: Renal Tubule: Adenoma												
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Kidney: Renal Tubule: Carcinoma												
Occasional descriptions of	T-1-1	0/49 (0%)	0/50 (0%)	00.00/	T-1-1	0/50 (0%)	0/50 (0%)	00.00/				
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Kidney: Renal Tubule: Carcinoma or Adenoma												
		0/49 (0%)	0/50 (0%)	OD 00/		0/50 (0%)	0/50 (0%)	05 00/				
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Kidney: Renal Tubule: Lipoma												
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Kidney: Renal Tubule: Liposarcoma												
		0/49 (0%)	0/50 (0%)	OD 00/		0/50 (0%)	0/50 (0%)	05 00/				
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: Wistar-Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 14

			Male				Female					
*Liver: Cholangioma 0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)												
Occupation and desired	T-1-1	0/49 (0%)	0/50 (0%)	OD 00/	T-1-1	0/50 (0%)	0/50 (0%)	00.00/				
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Liver: Hemangioma												
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Liver: Hepatocellular Adenon	na											
		3/49 (6%)	0/50 (0%)			3/50 (6%)	1/50 (2%)					
Overall Incidence	Total	3/99 (3.03%)	Mean 3.06%	SD 4.33%	Total	4/100 (4%)	Mean 4%	SD 2.83%				
*Liver: Hepatocellular Carcino												
		3/49 (6%)	0/50 (0%)			3/50 (6%)	1/50 (2%)					
Overall Incidence	Total	3/99 (3.03%)	Mean 3.06%	SD 4.33%	Total	4/100 (4%)	Mean 4%	SD 2.83%				
*Liver:		ular Adenoma, or Hepatok										
		3/49 (6%)	0/50 (0%)			3/50 (6%)	1/50 (2%)					
Overall Incidence	Total	3/99 (3.03%)	Mean 3.06%	SD 4.33%	Total	4/100 (4%)	Mean 4%	SD 2.83%				
*Lung: Alveolar/Bronchiolar A	denoma	(45.)	(0.5)			2/20 (00)						
		0/49 (0%)	0/50 (0%)	00.00/	-	0/50 (0%)	0/50 (0%)	00.00/				
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups **Route:** GAVAGE Report Date: 08/04/2016

Page: 15

Species: RATS Strain: Wistar-Han

Vehicle: CORN OIL

Length of Study: CHRONIC

			Male			Female				
*Lung: Alveolar/Bronchiolar Card	cinoma or Alv	eolar/Bronchiolar Adenoi	na							
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
#Lymph Node: Hemangioma										
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
#Lymph Node, Mandibular: Hemangioma										
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
#Lymph Node, Mesenteric: Hemangioma		4/40 (00)	4/50 (00)			0/50 (00/)	0/50 (00())			
Overall Incidence	Total	1/49 (2%) 2/99 (2.02%)	1/50 (2%) Mean 2.02%	SD 0.03%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
#Lymph Node, Mesenteric: Hemangiosarcoma										
Overall Incidence	Total	7/49 (14%) 8/99 (8.08%)	1/50 (2%) Mean 8.14%	SD 8.69%	Total	2/50 (4%) 3/100 (3%)	1/50 (2%) Mean 3%	SD 1.41%		
#Mammary Gland: Adenoma										
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 4/100 (4%)	4/50 (8%) Mean 4%	SD 5.66%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 16

			Male		1/50 (2%) 4/50 (8%) Total 5/100 (5%) Mean 5% SD 4.2 9/50 (18%) 8/50 (16%) Total 17/100 (17%) Mean 17% SD 1.4 9/50 (18%) 12/50 (24%) Total 21/100 (21%) Mean 21% SD 4.2 10/50 (20%) 12/50 (24%) Total 22/100 (22%) Mean 22% SD 2.8			e		
#Mammary Gland: Carcinoma										
		0/49 (0%)	0/50 (0%)			1/50 (2%)	1/50 (2%)			
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%		, ,		SD 0%		
Mammary Gland: Carcinoma or Adenoma										
		0/49 (0%)	0/50 (0%)			1/50 (2%)	4/50 (8%)			
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	5/100 (5%)	Mean 5%	SD 4.24%		
#Mammary Gland: Fibroadenoma										
		0/49 (0%)	1/50 (2%)			` '	8/50 (16%)			
Overall Incidence	Total	1/99 (1.01%)	Mean 1%	SD 1.41%		, ,		SD 1.41%		
Mammary Gland: Fibroma, Fibroadenoma										
		0/49 (0%)	1/50 (2%)			` '	, ,	05 4 0 404		
Overall Incidence	Total	1/99 (1.01%)	Mean 1%	SD 1.41%		, ,		SD 4.24%		
Mammary Gland: Fibroma, Fibroadenoma	, Carcinoma, o									
		0/49 (0%)	1/50 (2%)			` ,	, ,			
Overall Incidence	Total	1/99 (1.01%)	Mean 1%	SD 1.41%	Total	22/100 (22%)	Mean 22%	SD 2.83%		
Mesentery: Hemangiosarcoma										
		0/49 (0%)	0/50 (0%)		_	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 08/04/2016

Species: RATS
Strain: Wistar-Han

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
#Mesentery: Lipoma								
		1/49 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	0/100 (0%)	Mean 0%	SD 0%
#Mesentery: Schwannoma Malignant								
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Nose: Adenoma								
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Nose: Chondroma								
		0/49 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Nose: Olfactory Neuroblastoma								
•		0/49 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Oral Cavity (Oral Mucosa, To Squamous Cell Carcinoma	ongue, Phar	ynx, Tooth, Gingiva):						
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date: 08/04/2016

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Species: RATS
Strain: Wistar-Han

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
#Oral Cavity (Oral Mucos Squamous Cell Carcin		Squamous, or Papilloma						
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Oral Mucosa: Squamous Cell Carcin	oma							
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Ovary: Adenoma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Ovary: Cystadenoma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Ovary: Granulosa Cell Tumor	Benign							
Overall Incidence					Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
Ovary: Granulosa Cell Tumor	Malignant							
Overall Incidence					Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: Wistar-Han

Species: RATS

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

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			Male				Female	
*Ovary: Granulosa Cell Tumor: Be	enign, Maligna	ant, NOS				-()	(20)	
Overall Incidence					Total	2/50 (4%) 3/100 (3%)	1/50 (2%) Mean 3%	SD 1.41%
*Ovary: Granulosa-Theca Tumor I	Malignant							
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Sex Cord Stromal Tumor,								
Overall Incidence					Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%
*Ovary: Tubulostromal Adenoma						0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%
*Pancreas: Adenoma								
Overall Incidence	Total	1/46 (2%) 2/96 (2.08%)	1/50 (2%) Mean 2.09%	SD 0.12%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pancreas: Carcinoma or Adenoma		4/46 (20%)	1/50 /00/			0/50 /00/\	0/50 (00/)	
Overall Incidence	Total	1/46 (2%) 2/96 (2.08%)	1/50 (2%) Mean 2.09%	SD 0.12%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: Wistar-Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 20

		Male Female				1/49 (2%) 0/48 (0%) Total 1/97 (1.03%) Mean 1.02% SD 3 23/50 (46%) 21/50 (42%) Total 44/100 (44%) Mean 44% SD 3 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 23/50 (46%) 21/50 (42%) Total 44/100 (44%) Mean 44% SD 3 1/50 (2%) 4/50 (8%)		
*Parathyroid Gland: Adenoma								
		2/47 (4%)	0/45 (0%)			1/49 (2%)	0/48 (0%)	
Overall Incidence	Total	2/92 (2.17%)	Mean 2.13%	SD 3.01%	Total	1/97 (1.03%)	Mean 1.02%	SD 1.44%
*Pituitary Gland: Pars Distal Adenoma	is or Unspec	ified Site:						
		19/49 (39%)	21/50 (42%)			23/50 (46%)	21/50 (42%)	
Overall Incidence	Total	40/99 (40.4%)	Mean 40.39%	SD 2.28%	Total	44/100 (44%)	Mean 44%	SD 2.83%
*Pituitary Gland: Pars Distal Carcinoma	is or Unspec							
		0/49 (0%)	0/50 (0%)			` '	` '	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%		, ,		SD 0%
*Pituitary Gland: Pars Distal Carcinoma or Adenoma								
		19/49 (39%)	21/50 (42%)			23/50 (46%)	21/50 (42%)	
Overall Incidence	Total	40/99 (40.4%)	Mean 40.39%	SD 2.28%		` ,		SD 2.83%
*Pituitary Gland: Pars Interm Adenoma								
		0/49 (0%)	2/50 (4%)			1/50 (2%)	4/50 (8%)	
Overall Incidence	Total	2/99 (2.02%)	Mean 2%	SD 2.83%	Total	5/100 (5%)	Mean 5%	SD 4.24%
*Pituitary Gland: Pars Intern Carcinoma or Adenoma	nedia:							
		0/49 (0%)	2/50 (4%)			1/50 (2%)	4/50 (8%)	
Overall Incidence	Total	2/99 (2.02%)	Mean 2%	SD 2.83%	Total	5/100 (5%)	Mean 5%	SD 4.24%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date: 08/04/2016

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Species: RATS
Strain: Wistar-Han

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
*Prostate: Adenoma Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%				
*Prostate: Carcinoma		0/49 (0%)	0/50 (0%)					
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%				
*Prostate: Carcinoma or Adenoma		0/49 (0%)	0/50 (0%)					
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%				
*Salivary Glands: Adenoma		1/46 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/96 (1.04%)	Mean 1.09%	SD 1.54%	Total	0/100 (0%)	Mean 0%	SD 0%
*Salivary Glands: Carcinoma			•••••					
Overall Incidence	Total	0/46 (0%) 0/96 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
*Salivary Glands: Carcinoma or Adenoma								
Overall Incidence	Total	1/46 (2%) 1/96 (1.04%)	0/50 (0%) Mean 1.09%	SD 1.54%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 22

			Male				Female	
*Salivary Glands: Myoepithelioma								
Overall Incidence	Total	0/46 (0%) 1/96 (1.04%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Salivary Glands: Schwannoma Malignant		0/46 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/96 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma		0/49 (0%)	0/50 /00/					
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Skeletal Muscle: Hemangiosarcoma		1/49 (2%)	0/50 (0%)			0/50 (0%)	0/50 (09/)	
Overall Incidence	Total	1/49 (2%) 1/99 (1.01%)	0/50 (0%) Mean 1.02%	SD 1.44%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skeletal Muscle: Sarcoma								
Overall Incidence	Total	0/49 (0%) 1/99 (1.01%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Basal Cell Adenoma	• • • • • • • • • • • • • • • • • • • •	4/40 (00)	0/50 /40/)			4/50 (00/)	0/50 (00/)	
Overall Incidence	Total	1/49 (2%) 3/99 (3.03%)	2/50 (4%) Mean 3.02%	SD 1.39%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: Wistar-Han

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 08/04/2016

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

Male **Female** #Skin: Basal Cell Adenoma or Basosquamous Tumor Benign 1/49 (2%)2/50 (4%)1/50 (2%)0/50 (0%)Total 3/99 (3.03%) Mean 3.02% SD 1.39% 1/100 (1%) Mean 1% SD 1.41% **Overall Incidence** Total #Skin: Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma (2%)2/50 (4%)1/50 (2%)0/50 (0%)**Overall Incidence** Mean 3.02% 1/100 (1%) Mean 1% SD 1.41% Total 3/99 (3.03%) SD 1.39% Total #Skin: **Basal Cell Carcinoma** 0/49 (0%)1/50 (2%)0/50 (0%)0/50 (0%)1/99 (1.01%) **Overall Incidence** Mean 1% SD 1.41% 0/100 (0%) Mean 0% SD 0% Total Total #Skin: Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) 0/49 1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/99 (1.01%) Mean 1% SD 1.41% 0/100 (0%) SD 0% Total Mean 0% #Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma 1/49 (2%)2/50 (4%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 3/99 (3.03%) Mean 3.02% SD 1.39% Total 1/100 (1%) Mean 1% SD 1.41% #Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma 3/49 (6%)7/50 (14%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 10/99 (10.1%) Mean 10.06% SD 5.57% Total 1/100 (1%) Mean 1% SD 1.41%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: Wistar-Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 24

			Male Female					
#Skin: Fibroma								
		1/49 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Fibroma, Fibrosarcoma,	Sarcoma, Myx	oma, Myxosarcoma, or F	ibrous Histiocytoma					
		1/49 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Fibrosarcoma	•••••							
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin:		a, or Fibrous Histiocytom						
•	. •	0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Fibrous Histiocytoma		•••••						
-		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Hamartoma						2(72)	(201)	
	-	0/49 (0%)	0/50 (0%)	00.00/	-	0/50 (0%)	0/50 (0%)	00.00/
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 25

			Male Female				0/50 (0%) 1/50 (2%) Total 1/100 (1%) Mean 1% SI 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% Total 0/100 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)		
#Skin: Hemangiosarcoma									
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` '	` ,	SD 1.41%	
#Skin: Keratoacanthoma		2/49 (4%)	4/50 (8%)			0/50 (0%)	0/50 (00/)		
Overall Incidence	Total	2/49 (4%) 6/99 (6.06%)	4/50 (8%) Mean 6.04%	SD 2.77%	Total	, ,	` '	SD 0%	
#Skin: Lipoma									
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` '	` ,	SD 0%	
#Skin: Liposarcoma		0/40 /00/)	0/50 (00/)			0/50 (00/)	0/50 (00)		
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	, ,	` '	SD 0%	
#Skin: Myxoma									
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	, ,	` ,	SD 0%	
#Skin: Neurofibrosarcoma or \$		nalignant or NOS)					0/50 (00)		
Overall Incidence	Total	0/49 (0%) 2/99 (2.02%)	2/50 (4%) Mean 2%	SD 2.83%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Version: Aug2016 Contract/Lab: All Laboratories

Strain: Wistar-Han

Species: RATS

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

nal Groups Report Date: 08/04/2016

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			Male		Female						
#Skin: Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS) 0/49 (0%) 2/50 (4%) 0/50 (0%) 0/50 (0%)											
Overall Incidence	Total	2/99 (2.02%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Skin: Schwannoma Malignant		0/49 (0%)	2/50 (4%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	2/99 (2.02%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Skin: Squamous Cell Carcinon	ma	0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Skin: Squamous Cell Carcinon or Carcinoma		Carcinoma, Basosquamou	ıs Tumor (malignant								
Overall Incidence	Total	0/49 (0%) 1/99 (1.01%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			
#Skin: Squamous Cell Papillom		0/49 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	1/99 (1.01%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Skin: Squamous Cell Papillom	a or Papilloma		4/50 (00)			0/50 /00/	0/50 (00/)				
Overall Incidence	Total	0/49 (0%) 1/99 (1.01%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: Wistar-Han

Species: RATS

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: CORN OIL

Page: 27

			Male	Female								
#Skin: Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma												
Overall Incidence	Total	2/49 (4%) 7/99 (7.07%)	5/50 (10%) Mean 7.04%	SD 4.18%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Skin: Squamous Cell Papilloma		or Keratoacanthoma										
Overall Incidence	Total	2/49 (4%) 7/99 (7.07%)	5/50 (10%) Mean 7.04%	SD 4.18%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Skin: Sebaceous Gland: Adenoma												
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Skin: Sebaceous Gland: Carcinoma or Adenoma		0/49 (0%)				0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/49 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
*Spleen: Hemangiosarcoma												
Overall Incidence	Total	1/47 (2%) 2/97 (2.06%)	1/50 (2%) Mean 2.06%	SD 0.09%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Stomach, Forestomach: Fibrosarcoma												
Overall Incidence	Total	1/49 (2%) 1/99 (1.01%)	0/50 (0%) Mean 1.02%	SD 1.44%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 28

			Male				Female	
#Stomach, Forestomach: Leiomyoma								
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Leiomyosarcoma								
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Sarcoma								
		0/49 (0%)	0/50 (0%)	05 00/		0/50 (0%)	0/50 (0%)	22.00/
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma								
		0/49 (0%)	0/50 (0%)	05 00/		0/50 (0%)	0/50 (0%)	22.00/
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma o	or Papillom							
		1/49 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Papilloma		4/40 (000)	0/50 (001)			0(50 (00))	0/50 (00)	
Occupation of James	T-1-1	1/49 (2%)	0/50 (0%)	OD 4 440/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: Wistar-Han

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 29

			Male				Female	
#Stomach, Glandular: Fibrosarcoma								
		1/49 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Leiomyosarcoma								
		0/49 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Stomach, Glandular: Sarcoma								
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Testes: Adenoma								
		2/49 (4%)	0/50 (0%)					
Overall Incidence	Total	2/99 (2.02%)	Mean 2.04%	SD 2.89%				
*Testes: Hemangiosarcoma								
		0/49 (0%)	0/50 (0%)					
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%				
*Thymus: Sarcoma								
		0/45 (0%)	0/49 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/94 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 30

Report Date: 08/04/2016

Species: RATS
Strain: Wistar-Han

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male			Female			
*Thymus: Thymoma Benign		0/45 (0%)	1/49 (2%)			0/50 (0%)	1/50 (2%)		
Overall Incidence	Total	1/94 (1.06%)	Mean 1.02%	SD 1.44%	Total	1/100 (1%)	Mean 1%	SD 1.41%	
*Thymus: Thymoma: Benign, Maligr	nant, NOS								
Overall Incidence	Total	0/45 (0%) 1/94 (1.06%)	1/49 (2%) Mean 1.02%	SD 1.44%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	
*Thyroid Gland: Carcinoma									
Overall Incidence	Total	0/45 (0%) 0/95 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/45 (0%) 0/95 (0%)	0/50 (0%) Mean 0%	SD 0%	
*Thyroid Gland: C-Cell: Adenoma									
Overall Incidence	Total	11/45 (24%) 16/95 (16.84%)	5/50 (10%) Mean 17.22%	SD 10.21%	Total	7/45 (16%) 14/95 (14.74%)	7/50 (14%) Mean 14.78%	SD 1.1%	
*Thyroid Gland: C-Cell: Carcinoma									
Overall Incidence	Total	0/45 (0%) 0/95 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/45 (0%) 0/95 (0%)	0/50 (0%) Mean 0%	SD 0%	
*Thyroid Gland: C-Cell: Carcinoma or Adenoma									
Overall Incidence	Total	11/45 (24%) 16/95 (16.84%)	5/50 (10%) Mean 17.22%	SD 10.21%	Total	7/45 (16%) 14/95 (14.74%)	7/50 (14%) Mean 14.78%	SD 1.1%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 31

			Male				Female	
Thyroid Gland: Follicular Cell Adenoma	:							
		1/45 (2%)	3/50 (6%)			1/45 (2%)	3/50 (6%)	
Overall Incidence	Total	4/95 (4.21%)	Mean 4.11%	SD 2.67%	Total	4/95 (4.21%)	Mean 4.11%	SD 2.67%
Гhyroid Gland: Follicular Cell: Сагсіпота	:							
		0/45 (0%)	0/50 (0%)			0/45 (0%)	0/50 (0%)	
verall Incidence	Total	0/95 (0%)	Mean 0%	SD 0%	Total	0/95 (0%)	Mean 0%	SD 0%
Thyroid Gland: Follicular Cell Carcinoma or Adenoma	:		0.50					
		1/45 (2%)	3/50 (6%)			1/45 (2%)	3/50 (6%)	
verall Incidence	Total	4/95 (4.21%)	Mean 4.11%	SD 2.67%	Total	4/95 (4.21%)	Mean 4.11%	SD 2.67%
Jrinary Bladder: Carcinoma or Papilloma		0/49 (0%)	1/50 (2%)			0/50 (0%)	1/50 (2%)	
verall Incidence	Total	1/99 (1.01%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
Jrinary Bladder: Papilloma								
		0/49 (0%)	1/50 (2%)			0/50 (0%)	1/50 (2%)	
verall Incidence	Total	1/99 (1.01%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
Jterus: Adenoma								
						1/50 (2%)	0/50 (0%)	
Overall Incidence					Total	1/100 (1%)	Mean 1%	SD 1.41%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: Wistar-Han

Toxicology Data Management System

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Report Date: 08/04/2016

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE
Vehicle: CORN OIL

Length of Study: CHRONIC

Male **Female #Uterus:** Carcinoma 1/50 (2%)3/50 (6%)**Overall Incidence** Total 4/100 (4%) Mean 4% SD 2.83% **#Uterus: Granular Cell Tumor Benign** 1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/100 (1%) Mean 1% SD 1.41% #Uterus: Hemangiosarcoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% #Uterus: Leiomyosarcoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% #Uterus: **Malignant Mixed Mullerian Tumor** 1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/100 (1%) Mean 1% SD 1.41% #Uterus: **Polyp Stromal** 3/50 (6%)2/50 (4%)**Overall Incidence** Total 5/100 (5%) Mean 5% SD 1.41%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: Wistar-Han

Species: RATS

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 33

	Male			Female	
#Uterus: Sarcoma Stromal			0/50 (00/)	0/50 (00/)	
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Sarcoma Stromal or Polyp Stromal					
Overall Incidence		Total	3/50 (6%) 5/100 (5%)	2/50 (4%) Mean 5%	SD 1.41%
#Uterus: Schwannoma Malignant					
Overall Incidence		Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
#Uterus: Squamous Cell Papilloma			0/50 (0%)	0/50 (0%)	
Overall Incidence		Total	0/100 (0%)	Mean 0%	SD 0%
#Vagina: Fibrosarcoma					
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Vagina: Leiomyoma					
Overall Incidence		Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 34

			Male			Female		
#Vagina: Polyp						0/50 (0%)	0/50 (00/)	
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma or Adenoma								
		0/49 (0%)	0/50 (0%)	05 00/		0/50 (0%)	0/50 (0%)	25
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 35

Report Date: 08/04/2016

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical			
Male										
Battelle Columbus Laboratory	052020303	07/18/07	727	50(3)	35(687)	632.7	Green Tea Extract			
Female										
Battelle Columbus Laboratory	052020303	07/19/07	729	50(5)	26(671)	369.7	Green Tea Extract			

Species: RATS

Strain: Wistar-Han

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

Page: 36

			Male	Female				
#All Organs: Benign Tumors Overall Incidence	Total	26/50 (52%) 26/50 (52%)	Mean 52%	SD 0%	Total	38/50 (76%) 38/50 (76%)	Mean 76%	SD 0%
#All Organs: Malignant Tumors		12/50 (24%)				16/50 (32%)		
Overall Incidence	Total	12/50 (24%)	Mean 24%	SD 0%	Total	16/50 (32%)	Mean 32%	SD 0%
#All Organs: Malignant and Benign T	umors	36/50 (72%)				43/50 (86%)		
Overall Incidence	Total	36/50 (72%)	Mean 72%	SD 0%	Total	43/50 (86%)	Mean 86%	SD 0%
#All Organs: Hemangioma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma		0/50 (0%)				2/50 (4%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
#All Organs: Hemangiosarcoma or H	lemangioma	0/50 (00/)				0/50 /40/		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: Wistar-Han

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 08/04/2016

or Incidence for Selected Control Animal G

Route: GAVAGE

Vehicle: WATER

Length of Study: CHRONIC

			Male		Female			
#All Organs: Histiocytic Sarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Leukemia: Lymphocyti	c, Monocytic, Mo	ononuclear, or Undiffere	ntiated					
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs:	Histiocytic, Lymi	phocytic, Mixed, NOS, o	r Undifferentiated Ce	ell Type				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
	Total	0/50 (0%) 0/50 (0%)			Total	1/50 (2%)	Mean 2%	SD 0%
Overall Incidence #All Organs: Mesothelioma: Benign	Total	0/50 (0%) 0/50 (0%)			Total Total	` '	Mean 2% Mean 0%	SD 0%
Overall Incidence #All Organs:	Total , Malignant, NOS Total	0/50 (0%) 0/50 (0%) 2/50 (4%)	Mean 0%	SD 0%		1/50 (2%) ´ ´		
Overall Incidence #All Organs: Mesothelioma: Benign, Overall Incidence #All Organs: Mesothelioma: Maligna	Total , Malignant, NOS Total	0/50 (0%) 0/50 (0%) 2/50 (4%) 2/50 (4%)	Mean 0% Mean 4%	SD 0%	Total	1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
Overall Incidence #All Organs: Mesothelioma: Benign, Overall Incidence #All Organs:	Total , Malignant, NOS Total	0/50 (0%) 0/50 (0%) 2/50 (4%) 2/50 (4%)	Mean 0%	SD 0%		1/50 (2%) 0/50 (0%) 0/50 (0%)		
Overall Incidence #All Organs: Mesothelioma: Benign, Overall Incidence #All Organs: Mesothelioma: Maligna	Total , Malignant, NOS Total	0/50 (0%) 0/50 (0%) 2/50 (4%) 2/50 (4%)	Mean 0% Mean 4%	SD 0%	Total	1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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Report Date: 08/04/2016

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups **Route:** GAVAGE

Species: RATS
Strain: Wistar-Han

Vehicle: WATER

Length of Study: CHRONIC

			Male			Female			
#All Organs: Osteosarcoma		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#All Organs: Osteosarcoma or Osteoma		2/50 (4%)				0/50 (0%)			
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Adrenal Cortex: Adenoma		1/50 /20/)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Adrenal Cortex: Carcinoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Adrenal Medulla: Pheochromocytoma Benigr									
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
*Adrenal Medulla: Pheochromocytoma Compl	ex	0/50 (/0//)				0/50 (09/)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 39

			Male			Female						
*Adrenal Medulla: Pheochromocytoma Malignant												
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
*Adrenal Medulla: Pheochromocytoma: Be												
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%				
#Blood Vessel: Hemangiosarcoma		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Bone Marrow: Hemangiosarcoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
#Bone: Osteoma				30 0%	i Otal		iviean 0%	30 0%				
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
#Bone: Osteosarcoma		1/50 (2%)				0/50 (0%)						
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 40

				Male			Female			
#Bone: Osteosarcoma or Osteoma		,								
Overall Incidence	Total	2/50 2/50 (4%)	(4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Bone: Sarcoma										
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Brain: Glioma		0/50	(00()				0/50 (00/)			
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Brain: Glioma Malignant			(2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Brain: Granular Cell Tumor Benign										
Overall Incidence	Total	2/50 2/50 (4%)	(4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Brain: Granular Cell Tumor Maligna	ant	0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	(370)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: Wistar-Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 41

				Male			Female			
*Brain: Meningioma Malignant										
		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Brain: Meningioma: Benign, Malig	nant. NOS									
	iuiii, itoo	0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Brain: Oligodendroglioma Benign		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Brain: Oligodendroglioma, Glioma										
		1/50	(2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Clitoral/Preputial Gland: Carcinoma										
		1/50	(2%)				0/49 (0%)			
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	
*Clitoral/Preputial Gland: Carcinoma or Adenoma										
		1/50	(2%)				0/49 (0%)			
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 42

			Male				Female			
*Heart: Schwannoma Benign										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Heart: Schwannoma NOS										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Duodenum: Fibroma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Duodenum: Leiomyosarcoma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Jejunum: Leiomyoma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Jejunum: Leiomyosarcoma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 43

			Male			Female			
#Intestine Small: Site Unspec	cified:								
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Site Unspec Leiomyoma	cified:								
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Site Unspec Leiomyosarcoma						(70)			
Overall Incidence	Tatal	0/50 (0%)	Mana 00/	CD 00/	Tatal	1/50 (2%)	Mana 20/	CD 00/	
Overali incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
*Islets, Pancreatic: Adenoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Islets, Pancreatic: Carcinoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Islets, Pancreatic: Carcinoma or Adenoma	••••								
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 44

			Male				Female				
*Kidney: Pelvis and Transitional Epithelium: Papilloma											
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Kidney: Renal Tubule: Adenoma											
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Kidney: Renal Tubule: Carcinoma											
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Kidney: Renal Tubule: Carcinoma or Adenoma						0/50 (09/)					
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Kidney: Renal Tubule: Lipoma				•••••							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%			
*Kidney: Renal Tubule: Liposarcoma											
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 45

				Male			Female			
*Liver: Cholangioma										
			(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Me	ean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Liver: Hemangioma										
			(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Me	ean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Liver: Hepatocellular Adenoma		0/50	(00/)				4/50 (00()			
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	ean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
		, ,				·····	1/30 (2/0)			
*Liver: Hepatocellular Carcinoma	or Hepatocel	lular Adenoma								
			(0%)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)		ean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
*Liver: Hepatocellular Carcinoma,		lar Adenoma, or								
			(0%)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)	Me	ean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
*Lung: Alveolar/Bronchiolar Aden	oma	0/50	(00/)				0/50 /00/			
Overell Incidence	Total		(0%)	on 00/	CD 00/	Total	0/50 (0%)	Maan OO/	CD 00/	
Overall Incidence	Total	0/50 (0%)	IVIE	ean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 46

			Male	Female						
*Lung: Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma 0/50 (0%) 0/50 (0%)										
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Lymph Node: Hemangioma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Lymph Node, Mandibular: Hemangioma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Lymph Node, Mesenteric: Hemangioma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Lymph Node, Mesenteric: Hemangiosarcoma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%		
#Mammary Gland: Adenoma		0/50 (0%)				2/50 (49/)				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: Wistar-Han

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 47

			Male			Female			
#Mammary Gland: Carcinoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	6/50 (12%) 6/50 (12%)	Mean 12%	SD 0%	
#Mammary Gland: Carcinoma or Adenoma							•••••	•••••	
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	8/50 (16%) 8/50 (16%)	Mean 16%	SD 0%	
#Mammary Gland: Fibroadenoma		2/20 (201)				(000)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	11/50 (22%) 11/50 (22%)	Mean 22%	SD 0%	
#Mammary Gland: Fibroma, Fibroadenoma o						44/50 (000)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	11/50 (22%) 11/50 (22%)	Mean 22%	SD 0%	
#Mammary Gland: Fibroma, Fibroadenoma, (Adenoma							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	15/50 (30%) 15/50 (30%)	Mean 30%	SD 0%	
#Mesentery: Hemangiosarcoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 48

				Male			Female			
#Mesentery: Lipoma										
		,	0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Mesentery: Schwannoma Malignant										
Overall Incidence	Total	,	2%)	Maan 20/	CD 00/	Total	0/50 (0%)	Maan 00/	SD 0%	
Overali incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	2D 0%	
*Nose: Adenoma		0/50	(00/)				0/40 (09/)			
Overall Incidence	Total	0/50 (0/50 (0%)	0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	
*Nose: Chondroma		0/50 (0%)				0/49 (0%)			
Overall Incidence	Total	0/50 (0%)	0 76)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	
*Nose: Olfactory Neuroblastoma										
		,	0%)				0/49 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	
#Oral Cavity (Oral Mucosa, To Squamous Cell Carcinoma	ongue, Phary	nx, Tooth, Gingi	va):							
			2%)				1/50 (2%)			
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Version: Aug2016 Contract/Lab: All Laboratories

Strain: Wistar-Han

Species: RATS

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Report Date: 08/04/2016

Page: 49

			Male			Female				
#Oral Cavity (Oral Mucosa Squamous Cell Carcino						1/50 (2%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
#Oral Mucosa: Squamous Cell Carcino	ma									
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%		
*Ovary: Adenoma						0/50 /00/)				
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Ovary: Cystadenoma						0/50 (0%)				
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%		
*Ovary: Granulosa Cell Tumor B	enign									
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Ovary: Granulosa Cell Tumor N	lalignant					0/50 /00/				
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Version: Aug2016 Contract/Lab: All Laboratories

Strain: Wistar-Han

Species: RATS

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Page: 50

			Male			Female				
*Ovary: Granulosa Cell Tumor: Be	enign, Maligna	nt, NOS								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Ovary: Granulosa-Theca Tumor I	Malignant									
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Ovary: Sex Cord Stromal Tumor,	Benign					0/50 (00)				
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Ovary: Tubulostromal Adenoma Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Pancreas: Adenoma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Pancreas: Carcinoma or Adenoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 51

			Male			Female			
*Parathyroid Gland: Adenoma									
		0/47 (0%)				0/47 (0%)			
Overall Incidence	Total	0/47 (0%)	Mean 0%	SD 0%	Total	0/47 (0%)	Mean 0%	SD 0%	
*Pituitary Gland: Pars Dist Adenoma	alis or Unspeci	fied Site:							
		17/50 (34%)				32/50 (64%)			
Overall Incidence	Total	17/50 (34%)	Mean 34%	SD 0%	Total	32/50 (64%)	Mean 64%	SD 0%	
*Pituitary Gland: Pars Dist		fied Site:							
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Pituitary Gland: Pars Dist Carcinoma or Adenoma									
		17/50 (34%)				32/50 (64%)			
Overall Incidence	Total	17/50 (34%)	Mean 34%	SD 0%	Total	32/50 (64%)	Mean 64%	SD 0%	
*Pituitary Gland: Pars Intel Adenoma									
		1/50 (2%)				2/50 (4%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	
*Pituitary Gland: Pars Intel Carcinoma or Adenoma									
		1/50 (2%)				2/50 (4%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: Wistar-Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 52

			Male				Female	
*Prostate: Adenoma		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%				
*Prostate: Carcinoma		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%				
*Prostate: Carcinoma or Adenoma		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%				
*Salivary Glands: Adenoma		0/50 (0%)				0/49 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Salivary Glands: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%
*Salivary Glands: Carcinoma or Adenoma		0/50 (0%)				0/49 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: Wistar-Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 53

				Male				Female	
*Salivary Glands: Myoepithelioma									
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%
*Salivary Glands: Schwannoma Malignant			(004)						
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma			(00/)						
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Hemangiosarcoma			(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	, ,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Sarcoma									
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma		2/50	(4%)				0/50 (0%)		
Overall Incidence	Total	2/50 (4%)	(470)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: Wistar-Han

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Page: 54

Report Date: 08/04/2016

Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
#Skin:		T B						
Basal Cell Adenoma or B	asosquamous	2/50 (4%)				0/50 (0%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin:								
Basal Cell Adenoma, Bas	sosquamous Ti		pithelioma					
		2/50 (4%)		05.00/		0/50 (0%)		00.007
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin:	D	- T / N	06)					
Basal Cell Carcinoma or	basosquamou	0/50 (0%)	03)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin:								
Basal Cell Carcinoma, Ba		oma, Basosquamous Tun	nor (benign, maligna	ant or				
		2/50 (4%)				0/50 (0%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal or Sq. Cell Carcino Adenoma, Papilloma, Sq				ma,		0/50 (0%)		
Overall Incidence	Total	6/50 (12%)	Mean 12%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
						` '		32 0/0

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 55

			Male				Female			
#Skin: Fibroma										
		1/50 (2%)				0/50 (0%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Fibroma, Fibrosarcoma	, Sarcoma, Myxo	oma, Myxosarcoma, or	Fibrous Histiocytoma	ı						
,		1/50 (2%)	•			0/50 (0%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Fibrosarcoma										
• " ' '	-	0/50 (0%)		OD 00/	-	0/50 (0%)	14 00/	05 00/		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Fibrosarcoma, Sarcoma	a, Myxosarcoma	, or Fibrous Histiocyton	na							
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Fibrous Histiocytoma										
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Hamartoma		4/50 (001)				0/50 (00/)				
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
Overall illustrate	IUlai	1/30 (2/0)	IVICALI Z/0	0 /0	ı Ulai	0/30 (0/0)	IVICALI U/0	30 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: Wistar-Han

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 08/04/2016

Species: RATS

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female			
#Skin: Hemangiosarcoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Skin: Keratoacanthoma Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Skin: Lipoma Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Skin: Liposarcoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Skin: Myxoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Skin: Neurofibrosarcoma or S Overall Incidence	Schwannoma (m a Total	alignant or NOS) 2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han
Length of Study: CHRONIC

Toxicology Data Management System

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Report Date: 08/04/2016

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

#Skin: Neurofibrosarcoma, Neurofibro				Female							
Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS) 2/50 (4%) 2/50 (4%)											
Overall Incidence T	Total	2/50 (4%)	Mean 4%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%			
#Skin: Schwannoma Malignant		2/50 (4%)				2/50 (4%)					
Overall Incidence T	Γotal	2/50 (4%)	Mean 4%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%			
#Skin: Squamous Cell Carcinoma		1/50 (2%)				0/50 (0%)					
Overall Incidence T	Γotal	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Skin: Squamous Cell Carcinoma, Bas or Carcinoma	sal Cell Ca	rcinoma, Basosquamo	us Tumor (malignan	t or NOS),		0/50 (0%)					
Overall Incidence T	Γotal	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Skin: Squamous Cell Papilloma		1/50 (2%)				0/50 (0%)					
Overall Incidence T	Γotal	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Skin: Squamous Cell Papilloma or Pa	apilloma	4/50 (20%)				0/50 (00/)					
Overall Incidence T	Γotal	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: Wistar-Han

Species: RATS

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

mal Groups Report Date: 08/04/2016

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			Male			Female			
#Skin: Squamous Cell Papilloma	a, Papilloma, S	equamous Cell Carcinom 4/50 (8%)	a or Keratoacanthor	na		0/50 (0%)			
Overall Incidence	Total	4/50 (8%)	Mean 8%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Squamous Cell Papilloma						0/50 (0%)			
Overall Incidence	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Skin: Sebaceous Gland: Adenoma		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Sebaceous Gland: Carcinoma or Adenoma		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Spleen: Hemangiosarcoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Stomach, Forestomach: Fibrosarcoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: Wistar-Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 59

				Male				Female			
#Stomach, Forestomach: Leiomyoma											
		0/50	(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Stomach, Forestomach: Leiomyosarcoma											
		1/50	(2%)				0/50 (0%)				
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Stomach, Forestomach: Sarcoma											
		0/50	(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Stomach, Forestomach: Squamous Cell Carcinoma											
		0/50	(0%)				1/50 (2%)				
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
#Stomach, Forestomach: Squamous Cell Carcinoma	or Papilloma	a Squamous									
·	•	0/50	(0%)				1/50 (2%)				
Overall Incidence	Total	0/50 (0%)	. ,	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
#Stomach, Forestomach: Squamous Cell Papilloma											
		0/50	(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 60

			Male				Female	
#Stomach, Glandular: Fibrosarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Leiomyosarcoma								
		0/50 (0%)	••	05.00/		0/50 (0%)		00.007
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Sarcoma		0/50 (00/)				0/50 (00)		
Overell Incidence	Tatal	0/50 (0%)	Mana 00/	CD 00/	Tatal	0/50 (0%)	Mana 00/	CD 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Testes: Adenoma		0(50 (40))						
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%				
		` '						
*Testes: Hemangiosarcoma								
		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%				
*Thymus: Sarcoma								
		0/49 (0%)				0/49 (0%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 61

			Male				Female	
*Thymus: Thymoma Benign	Tatal	2/49 (4%)	Mary 4 000/	CD 00/	Takal	3/49 (6%)	Mann C 400′	CD 00/
Overall Incidence	Total	2/49 (4.08%)	Mean 4.08%	SD 0%	Total	3/49 (6.12%)	Mean 6.12%	SD 0%
*Thymus: Thymoma: Benign, Malign	ant, NOS							
Overall Incidence	Total	2/49 (4%) 2/49 (4.08%)	Mean 4.08%	SD 0%	Total	3/49 (6%) 3/49 (6.12%)	Mean 6.12%	SD 0%
*Thyroid Gland: Carcinoma		0/50 (00/)				0(50 (00))		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Adenoma		4/50 (8%)				3/50 (6%)		
Overall Incidence	Total	4/50 (8%)	Mean 8%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		4/50 (99/)				A/EO (99/)		
Overall Incidence	Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%	Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 62

				Male				Female	
*Thyroid Gland: Follicular Cell: Adenoma									
			(0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Thyroid Gland: Follicular Cell: Carcinoma									
			(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma		0/50	(0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Urinary Bladder: Carcinoma or Papilloma			(0%)				0/49 (0%)		
Overall Incidence	Total	0/50 (0%)	` ,	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Papilloma									
			(0%)				0/49 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
#Uterus: Adenoma									
						+	0/50 (0%)		00.00/
Overall Incidence						Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: Wistar-Han

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Mean 0%

Report Date: 08/04/2016

SD 0%

SD 0%

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

#Uterus:
Carcinoma

Overall Incidence

Total 3/50 (6%)

#Uterus:
Granular Cell Tumor Benign

0/50

0/50 (0%)

Total

(0%)

#Uterus:	
Hemangiosarcoma	

		0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%

#Uterus:

Overall Incidence

Leiomyosarcoma 0/50 (0%)

Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%

#Uterus:

Malignant Mixed Mullerian Tumor
0/50 (0%)

Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%

#Uterus:

Polyp Stromal

3/50 (6%)

		3/30 (0/0)		
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: Wistar-Han

Species: RATS

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

> Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

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	Male			Female	
#Uterus: Sarcoma Stromal					
Overall Incidence		Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Uterus: Sarcoma Stromal or Polyp Stromal					
Overall Incidence		Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%
#Uterus: Schwannoma Malignant					
Overall Incidence		Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Uterus: Squamous Cell Papilloma					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Vagina: Fibrosarcoma		•••••	•••••		
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Vagina: Leiomyoma					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 65

			Male				Female	
#Vagina: Polyp						4/50 (00()		
Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Zymbal's Gland: Carcinoma		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma or Adenoma								
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 08/04/2016

Species: RATS
Strain: Wistar-Han

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Northwest	052060103	09/22/08	729	50(5)	30(672)	606.7	Antimony trioxide
Battelle Northwest	052072503	08/17/09	729	50(5)	36(692)	615.2	2,3-Butanedione
Battelle Northwest	052051503	04/14/08	729	50(5)	33(688)	602.8	Metal Working Fluids: CIMSTAR 3800
Battelle Northwest	052052303	07/20/09	729	50(5)	36(696)	622.2	Metal Working Fluids: TRIM VX
					Female		
Battelle Northwest	052060103	09/22/08	730	50(5)	39(704)	395.6	Antimony trioxide
Battelle Northwest	052072503	08/17/09	731	50(5)	34(688)	400.0	2,3-Butanedione
Battelle Northwest	052051503	04/14/08	731	50(5)	35(700)	384.9	Metal Working Fluids: CIMSTAR 3800
Battelle Northwest	052052303	07/20/09	731	50(5)	30(681)	391.1	Metal Working Fluids: TRIM VX

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#All Organs: Benign Tumors								
		34/50 (68%) 24/50 (48%)	27/50 (54%)	32/50 (64%)		33/50 (66%) 42/50 (84%)	39/50 (78%)	42/50 (84%)
Overall Incidence	Total	117/200 (58.5%)	Mean 58.5%	SD 9.15%	Total	156/200 (78%)	Mean 78%	SD 8.49%
#All Organs: Malignant Tumors								
		6/50 (12%) 4/50 (8%)	13/50 (26%)	13/50 (26%)		17/50 (34%) 13/50 (26%)	12/50 (24%)	11/50 (22%)
Overall Incidence	Total	36/200 (18%)	Mean 18%	SD 9.38%	Total	53/200 (26.5%)	Mean 26.5%	SD 5.26%
#All Organs: Malignant and Benign T		36/50 (72%)	35/50 (70%)	37/50 (74%)		40/50 (80%)	40/50 (80%)	43/50 (86%)
		26/50 (52%)	33/30 (70%)	37/30 (74%)		47/50 (94%)	40/30 (80%)	43/30 (66%)
Overall Incidence	Total	134/200 (67%)	Mean 67%	SD 10.13%	Total	170/200 (85%)	Mean 85%	SD 6.63%
#All Organs: Hemangioma								
		1/50 (2%) 1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#All Organs: Hemangiosarcoma								
		3/50 (6%) 0/50 (0%)	3/50 (6%)	3/50 (6%)		1/50 (2%) 0/50 (0%)	2/50 (4%)	1/50 (2%)
Overall Incidence	Total	9/200 (4.5%)	Mean 4.5%	SD 3%	Total	4/200 (2%)	Mean 2%	SD 1.63%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#All Organs: Hemangiosarcoma or l	Hemangioma							
		4/50 (8%) 1/50 (2%)	4/50 (8%)	3/50 (6%)		1/50 (2%) 0/50 (0%)	3/50 (6%)	1/50 (2%)
Overall Incidence	Total	12/200 (6%)	Mean 6%	SD 2.83%	Total	5/200 (2.5%)	Mean 2.5%	SD 2.52%
#All Organs: Histiocytic Sarcoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 2/50 (4%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	2/200 (1%)	Mean 1%	SD 2%
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/50 (2%) 0/50 (0%) 1/200 (0.5%)	0/50 (0%) Mean 0.5%	0/50 (0%) SD 1%	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#All Organs:		0/50 (0%) 1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/50 (0%)	,	,
Overall Incidence #All Organs: Malignant Lymphoma:		0/50 (0%)	Mean 0.5%	SD 1%	Total	0/50 (0%)	,	,
#All Organs: Malignant Lymphoma:		0/50 (0%) 1/200 (0.5%) nphocytic, Mixed, NOS, or 0/50 (0%)	Mean 0.5%	SD 1%	Total Total	0/50 (0%) 0/200 (0%) 0/50 (0%)	Mean 0%	SD 0%
#All Organs: Malignant Lymphoma: Overall Incidence	Histiocytic, Lym	0/50 (0%) 1/200 (0.5%) aphocytic, Mixed, NOS, or 0/50 (0%) 1/50 (2%) 4/200 (2%)	Mean 0.5% Tundifferentiated Cel 3/50 (6%)	SD 1% I Type 0/50 (0%)		0/50 (0%) 0/200 (0%) 0/50 (0%) 1/50 (2%)	Mean 0%	SD 0% 2/50 (4%)
#All Organs: Malignant Lymphoma: Overall Incidence #All Organs:	Histiocytic, Lym	0/50 (0%) 1/200 (0.5%) aphocytic, Mixed, NOS, or 0/50 (0%) 1/50 (2%) 4/200 (2%)	Mean 0.5% Tundifferentiated Cel 3/50 (6%)	SD 1% I Type 0/50 (0%)		0/50 (0%) 0/200 (0%) 0/50 (0%) 1/50 (2%)	Mean 0%	SD 0% 2/50 (4%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: Wistar-Han

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 08/04/2016

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #All Organs: Mesothelioma: Malignant 0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)Overall Incidence Total 3/200 (1.5%) Mean 1.5% SD 1% Total 0/200 (0%) Mean 0% SD 0% #All Organs: Osteoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% Mean 0% Overall Incidence Total 0/200 (0%) SD 0% Total 0/200 (0%) SD 0% #All Organs: Osteosarcoma 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total 0/200 (0%) Mean 0% SD 0% #All Organs: Osteosarcoma or Osteoma 0/50 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total 0/200 (0%) Mean 0% SD 0% *Adrenal Cortex: Adenoma 3/50 2/50 (4%)(6%)2/50 (4%)0/50 (0%)1/50 (2%)2/50 (4%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 8/200 (4%) Mean 4% SD 1.63% Total 3/200 (1.5%) Mean 1.5% SD 1.91%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
*Adrenal Cortex: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Bo								4/40 (00/)
		1/49 (2%) 0/50 (0%)	1/50 (2%)	4/50 (8%)		0/49 (0%) 0/50 (0%)	3/50 (6%)	1/49 (2%)
Overall Incidence	Total	6/199 (3.02%)	Mean 3.01%	SD 3.46%	Total	4/198 (2.02%)	Mean 2.01%	SD 2.83%
*Adrenal Medulla: Pheochromocytoma Co								
		1/49 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/198 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma M	alignant							
		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	1/49 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%
*Adrenal Medulla: Pheochromocytoma: B	Benign, Complex	τ, Malignant, NOS						
		2/49 (4%) 0/50 (0%)	1/50 (2%)	4/50 (8%)		0/49 (0%) 0/50 (0%)	3/50 (6%)	2/49 (4%)
Overall Incidence	Total	7/199 (3.52%)	Mean 3.52%	SD 3.42%	Total	5/198 (2.53%)	Mean 2.52%	SD 3.01%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS Strain: Wistar-Han

Toxicology Data Management System

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Report Date: 08/04/2016

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Blood Vessel: Hemangiosarcoma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Bone Marrow: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Bone: Osteoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma or Osteoma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: Wistar-Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Bone: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Brain: Glioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	0/200 (0%)	Mean 0%	SD 0%
*Brain: Glioma Malignant								
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Granular Cell Tumor Be	enign							
		1/50 (2%) 0/50 (0%)	3/50 (6%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	1/50 (2%)	2/50 (4%)
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 2.83%	Total	4/200 (2%)	Mean 2%	SD 1.63%
*Brain: Granular Cell Tumor Ma	alignant							
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
*Brain: Meningioma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
*Brain: Meningioma: Benign, Mali								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma Benigi								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
*Brain: Oligodendroglioma, Gliom	na, or Astrocy	rtoma						
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
*Clitoral/Preputial Gland: Carcinoma					•••••			
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
*Clitoral/Preputial Gland: Carcinoma or Adenoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
*Heart: Schwannoma Benign								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
*Heart: Schwannoma NOS								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Fibroma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Leiomyosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: Wistar-Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
fIntestine Small: Jejunum: Leiomyoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Intestine Small: Jejunum: Leiomyosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspe Fibroma	ecified:							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspe Leiomyoma	ecified:							
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Intestine Small: Site Unspe Leiomyosarcoma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
*Islets, Pancreatic: Adenoma								
		0/50 (0%) 5/50 (10%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/49 (2%)
Overall Incidence	Total	5/200 (2.5%)	Mean 2.5%	SD 5%	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%
*Islets, Pancreatic: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Carcinoma or Adenoma								
		0/50 (0%) 5/50 (10%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/49 (2%)
Overall Incidence	Total	5/200 (2.5%)	Mean 2.5%	SD 5%	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%
*Kidney: Pelvis and Transition Papilloma	onal Epitheliu	um:						
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
'Kidney: Renal Tubule: Carcinoma								
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma								4/50 (001)
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
*Kidney: Renal Tubule: Lipoma								
·		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Liposarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Liver: Cholangioma	•							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	3/50 (6%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	3/200 (1.5%)	Mean 1.5%	SD 3%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Vehicle: AIR

Route: INHALATION

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			Male				Female	
Liver: Hemangioma								
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Liver: Hepatocellular Adenom	a							
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
*Liver: Hepatocellular Carcino Overall Incidence	ma or Hepatoce Total	ellular Adenoma 0/50 (0%) 1/50 (2%) 1/200 (0.5%)	0/50 (0%) Mean 0.5%	0/50 (0%) SD 1%	Total	1/50 (2%) 0/50 (0%) 1/200 (0.5%)	0/50 (0%) Mean 0.5%	0/50 (0%) SD 1%
Liver: Hepatocellular Carcino	ma, Hepatocellu	ılar Adenoma, or Hepatol						
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Lung: Alveolar/Bronchiolar Ad	denoma	0/50 (00/)	4/50 (00/)	4/50 (00()		0/50 (00()	0/50 (00)	0/50 (00/)
		3/50 (6%) 0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	5/200 (2.5%)	Mean 2.5%	SD 2.52%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups
Route: INHALATION

Report Date: 08/04/2016

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Species: RATS
Strain: Wistar-Han

Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
*Lung: Alveolar/Bronchiolar Carci	inoma or Alv	eolar/Bronchiolar Adeno	ma					
		3/50 (6%) 0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	5/200 (2.5%)	Mean 2.5%	SD 2.52%	Total	0/200 (0%)	Mean 0%	SD 0%
#Lymph Node: Hemangioma								
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Lymph Node, Mandibular: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Lymph Node, Mesenteric: Hemangioma								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Hemangiosarcoma						•••••		
		2/50 (4%) 0/50 (0%)	2/50 (4%)	3/50 (6%)		0/50 (0%) 0/50 (0%)	2/50 (4%)	1/50 (2%)
Overall Incidence	Total	7/200 (3.5%)	Mean 3.5%	SD 2.52%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: Wistar-Han

Toxicology Data Management System

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Report Date: 08/04/2016

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Male **Female** #Mammary Gland: Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)5/50 (10%) 2/50 (4%)0/50 (0%)4/50 (8%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 11/200 (5.5%) Mean 5.5% SD 4.43% #Mammary Gland: Carcinoma 0/50 (0%)1/50 (2%)0/50 (0%)5/50 (10%)4/50 (8%)(8%)0/50 (0%)4/50 (8%)Overall Incidence Total 1/200 (0.5%) Mean 0.5% SD 1% Total 17/200 (8.5%) Mean 8.5% SD 1% **#Mammary Gland:** Carcinoma or Adenoma 0/50 (0%)1/50 0/50 (0%)5/50 (10%)8/50 (16%) 6/50 (12%) 0/50 (0%)8/50 (16%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total 27/200 (13.5%) Mean 13.5% SD 3% #Mammary Gland: Fibroadenoma 0/50 (0%)0/50 (0%)0/50 (0%)7/50 (14%)13/50 (26%)9/50 (18%) 0/50 (0%)2/50 (4%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 31/200 (15.5%) Mean 15.5% SD 9.15% #Mammary Gland: Fibroma, Fibroadenoma or Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)7/50 (14%)15/50 (30%)(22%)0/50 (0%)6/50 (12%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 39/200 (19.5%) Mean 19.5% SD 8.23%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Mammary Gland: Fibroma, Fibroadenoma, C	arcinoma, o	r Adenoma						
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		10/50 (20%) 9/50 (18%)	15/50 (30%)	13/50 (26%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	47/200 (23.5%)	Mean 23.5%	SD 5.51%
#Mesentery: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mesentery: Lipoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mesentery: Schwannoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Nose: Adenoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
*Nose: Chondroma								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
*Nose: Olfactory Neuroblastoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Squamous Cell Carcinoma Overall Incidence	Total	0/50 (0%) 0/50 (0%) 1/200 (0.5%)	1/50 (2%) Mean 0.5%	0/50 (0%) SD 1%	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Oral Cavity (Oral Mucosa, T Squamous Cell Carcinoma	•	Squamous, or Papilloma						
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Oral Mucosa: Squamous Cell Carcinoma	a							
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Version: Aug2016 Contract/Lab: All Laboratories

Species: RATS

Strain: Wistar-Han

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 08/04/2016

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

	Male		Female					
*Ovary: Adenoma								
			2/50 (4%) 0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence		Total	2/200 (1%)	Mean 1%	SD 2%			
*Ovary: Cystadenoma								
			1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence		Total	1/200 (0.5%)	Mean 0.5%	SD 1%			
*Ovary: Granulosa Cell Tumor Benign								
			0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)			
Overall Incidence		Total	1/200 (0.5%)	Mean 0.5%	SD 1%			
Ovary: Granulosa Cell Tumor Malignant								
			0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)			
Overall Incidence		Total	1/200 (0.5%)	Mean 0.5%	SD 1%			
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS								
			0/50 (0%) 1/50 (2%)	0/50 (0%)	1/50 (2%)			
Overall Incidence		Total	2/200 (1%)	Mean 1%	SD 1.15%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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				Male						F	emale		
Ovary: Granulosa-Theca Tumor M	lalignant												
								0/50 0/50	(0%) (0%)	1/50	(2%)	0/50	(0%)
Overall Incidence							Total	1/200 (0.	.5%)	Mean	0.5%	SD	1%
*Ovary: Sex Cord Stromal Tumor, I	Benign												
								0/50 0/50	(0%) (0%)	0/50	(0%)	0/50	(0%)
Overall Incidence							Total	0/200 (0	0%)	Mea		SD	
*Ovary: Tubulostromal Adenoma	•••••							2/50	(4%)	1/50	(2%)	0/50	(0%)
								0/50	(4%)	1/50	(270)	0/30	(0%)
Overall Incidence							Total	3/200 (1.	.5%)	Mean	1.5%	SD 1.	.91%
'Pancreas: Adenoma													
		0/50 (0%) 1/50 (2%)	0/50	(0%)	1/50	(2%)		0/50 0/50	(0%) (0%)	0/50	(0%)	0/49	(0%)
Overall Incidence	Total	2/200 (1%)	Mean	1%	SD 1.15%	, 0	Total	0/199 (0	. ,	Mea	า 0%	SD	0%
Pancreas: Carcinoma or Adenoma													
		0/50 (0%) 1/50 (2%)	0/50	(0%)	1/50	(2%)		0/50 0/50	(0%) (0%)	0/50	(0%)	0/49	(0%)
Overall Incidence	Total	2/200 (1%)	Mean	1%	SD 1.15%	, 0	Total	0/199 (0	. ,	Mea	ո 0%	SD	0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male		Female				
*Parathyroid Gland: Adenoma									
		0/44 (0%) 0/39 (0%)	1/49 (2%)	0/43 (0%)		0/39 (0%) 1/42 (2%)	0/46 (0%)	0/47 (0%)	
Overall Incidence	Total	1/175 (0.57%)	Mean 0.51%	SD 1.02%	Total	1/174 (0.57%)	Mean 0.6%	SD 1.19%	
*Pituitary Gland: Pars Dis Adenoma	stalis or Unspec	cified Site:							
		14/50 (28%) 14/50 (28%)	9/50 (18%)	16/49 (33%)		19/50 (38%) 34/50 (68%)	26/50 (52%)	35/50 (70%)	
Overall Incidence	Total	53/199 (26.63%)	Mean 26.66%	SD 6.18%	Total	114/200 (57%)	Mean 57%	SD 15.01%	
Carcinoma Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	1/50 (2%) 0/50 (0%) 1/200 (0.5%)	0/50 (0%) Mean 0.5%	0/50 (0%) SD 1%	
Pituitary Gland: Pars Dis	stalis or Unspec	cified Site:							
Carcinoma or Adenoma	а								
Carcinoma or Adenoma	a	14/50 (28%) 14/50 (28%)	9/50 (18%)	16/49 (33%)		20/50 (40%) 34/50 (68%)	26/50 (52%)	35/50 (70%)	
	a Total	14/50 (28%)	9/50 (18%) Mean 26.66%	16/49 (33%) SD 6.18%	Total	` ,	26/50 (52%) Mean 57.5%	35/50 (70%) SD 14.18%	
Overall Incidence	Total	14/50 (28%) 14/50 (28%)	,	,	Total	34/50 (68%)	,	,	
Overall Incidence 'Pituitary Gland: Pars Int	Total	14/50 (28%) 14/50 (28%)	,	,	Total	34/50 (68%)	,	,	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
*Pituitary Gland: Pars Interm Carcinoma or Adenoma	nedia:							
		1/50 (2%) 1/50 (2%)	2/50 (4%)	2/49 (4%)		0/50 (0%) 1/50 (2%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	6/199 (3.02%)	Mean 3.02%	SD 1.18%	Total	3/200 (1.5%)	Mean 1.5%	SD 1%
*Prostate: Adenoma								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	1/50 (2%)				
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%				
*Prostate: Carcinoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%				
*Prostate: Carcinoma or Adenoma								
		1/50 (2%) 0/50 (0%)	1/50 (2%)	1/50 (2%)				
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1%				
*Salivary Glands: Adenoma				•••••	•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: Wistar-Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Salivary Glands: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Salivary Glands: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Salivary Glands: Myoepithelioma								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Salivary Glands: Schwannoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)				
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Skeletal Muscle: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma or E	Basosquamous	Tumor Benign						
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma, Ba								
.,		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups
Route: INHALATION

Report Date: 08/04/2016

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Species: RATS Strain: Wistar-Han

Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
#Skin: Basal Cell Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin:								
Basal Cell Carcinoma o	or Basosquamou	us Tumor (malignant or N 0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma, I NOS), or Trichoepitheli	Basal Cell Adendioma	oma, Basosquamous Tur	mor (benign, malignar	nt or 1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Basal Cell Carcinoma, I	Basal Cell Adendoma Total	•	, , ,		Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Basal Cell Carcinoma, NOS), or Trichoepitheli Dverall Incidence #Skin: Basal or Sq. Cell Carcin	Total	0/50 (0%) 0/50 (0%) 1/200 (0.5%) a, Basosq. Tumor (M or I	0/50 (0%) Mean 0.5% 3), Basal Cell Adenom	1/50 (2%) SD 1%	Total	0/50 (0%)	(,	(222,
Basal Cell Carcinoma, NOS), or Trichoepitheli Overall Incidence #Skin: Basal or Sq. Cell Carcin	Total	0/50 (0%) 0/50 (0%) 1/200 (0.5%)	0/50 (0%) Mean 0.5% 3), Basal Cell Adenom	1/50 (2%) SD 1%	Total	0/50 (0%)	(,	(222,
Basal Cell Carcinoma, I NOS), or Trichoepitheli Overall Incidence #Skin: Basal or Sq. Cell Carcin Adenoma, Papilloma, S	Total Total noma, Carcinom q Papilloma, Ke	0/50 (0%) 0/50 (0%) 1/200 (0.5%) a, Basosq. Tumor (M or I ratoacanthoma, Trichoep 1/50 (2%) 1/50 (2%) 7/200 (3.5%)	0/50 (0%) Mean 0.5% B), Basal Cell Adenomonithelioma 3/50 (6%) Mean 3.5%	1/50 (2%) SD 1% na, 2/50 (4%) SD 1.91%	Total	0/50 (0%) 0/200 (0%) 0/50 (0%)	Mean 0%	SD 0%
Basal Cell Carcinoma, NOS), or Trichoepitheli Dverall Incidence #Skin: Basal or Sq. Cell Carcin Adenoma, Papilloma, S Dverall Incidence	Total Total noma, Carcinom q Papilloma, Ke	0/50 (0%) 0/50 (0%) 1/200 (0.5%) a, Basosq. Tumor (M or I ratoacanthoma, Trichoep 1/50 (2%) 1/50 (2%) 7/200 (3.5%)	0/50 (0%) Mean 0.5% B), Basal Cell Adenomonithelioma 3/50 (6%) Mean 3.5%	1/50 (2%) SD 1% na, 2/50 (4%) SD 1.91%	Total	0/50 (0%) 0/200 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0% 0/50 (0%)
Basal Cell Carcinoma, NOS), or Trichoepitheli Overall Incidence #Skin: Basal or Sq. Cell Carcin Adenoma, Papilloma, S Overall Incidence	Total Total noma, Carcinom q Papilloma, Ke	0/50 (0%) 0/50 (0%) 1/200 (0.5%) a, Basosq. Tumor (M or I ratoacanthoma, Trichoep 1/50 (2%) 1/50 (2%) 7/200 (3.5%)	0/50 (0%) Mean 0.5% B), Basal Cell Adenomonithelioma 3/50 (6%) Mean 3.5%	1/50 (2%) SD 1% na, 2/50 (4%) SD 1.91%	Total	0/50 (0%) 0/200 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0% 0/50 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 90 Report Date: 08/04/2016

Species: RATS
Strain: Wistar-Han

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male		Female	
#Skin: Fibroma, Fibrosarcoma, S	Sarcoma, Myx	oma, Myxosarcoma, or Fi	brous Histiocytoma			
		2/50 (4%) 1/50 (2%)	2/50 (4%) 2/50 (4	,	2/50 (4%) 0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	7/200 (3.5%)	Mean 3.5% SD 1%	Total 2	/200 (1%) Mean 1%	SD 2%
#Skin: Fibrosarcoma						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2	,	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5% SD 1%		/200 (0%) Mean 0%	SD 0%
#Skin: Fibrosarcoma, Sarcoma, Overall Incidence	Myxosarcom a	0/50 (0%) 0/50 (0%) 0/50 (0%) 2/200 (1%)		,	0/50 (0%) 0/50 (0%) 0/50 (0%) //200 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Fibrous Histiocytoma		0/50 (0%)	1/50 (2%) 0/50 (0	0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/200 (0.5%)	Mean 0.5% SD 1%	Total 0	0/50 (0%) //200 (0%) Mean 0%	SD 0%
#Skin: Hamartoma						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0	,	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0% SD 0%	Total 0	/200 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: Wistar-Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Skin: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Keratoacanthoma								
		1/50 (2%) 1/50 (2%)	3/50 (6%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	6/200 (3%)	Mean 3%	SD 2%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Lipoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Liposarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Myxoma								
-		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: Wistar-Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Skin:								
Neurofibrosarcoma or Schv	vannoma (m	nalignant or NOS)						
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin:			-!' NOO\					
Neurofibrosarcoma, Neurof	ibroma, or	, . .	•	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Schwannoma Malignant								
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma				•••••			•••••	
1		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma, or Carcinoma	Basal Cell	Carcinoma, Basosquamo	ous Tumor (malignant o	or NOS),				
oi Carcinoma		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Skin: Squamous Cell Papilloma	a							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma	a or Papilloma							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Overall Incidence	Total	1/50 (2%) 1/50 (2%) 6/200 (3%)	3/50 (6%) Mean 3%	1/50 (2%) SD 2%	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		` '				0/200 (0%)	Mean 0%	SD 0%
#Skin:								
#Skin: Squamous Cell Papilloma	a, Papilloma, o	r Keratoacanthoma 1/50 (2%) 1/50 (2%)	3/50 (6%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Squamous Cell Papilloma Overall Incidence	Total	1/50 (2%)	3/50 (6%) Mean 3%	1/50 (2%) SD 2%	Total	` ,	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
-	Total	1/50 (2%) 1/50 (2%)	,	, ,	Total	0/50 (0%)	, ,	,
Squamous Cell Papilloma Overall Incidence #Skin: Sebaceous Gland:	Total	1/50 (2%) 1/50 (2%)	,	, ,	Total	0/50 (0%)	, ,	,

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Skin: Sebaceous Gland: Carcinoma or Adenoma								
		0/50 (0%) 1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
*Spleen: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Leiomyoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Stomach, Forestomach: Leiomyosarcoma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Stomach, Forestomach: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 1/200 (0.5%)	1/50 (2%) Mean 0.5%	0/50 (0%) SD 1%
#Stomach, Forestomach:								
•								
Squamous Cell Papilloma		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
•	Total	()	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	` ,	1/50 (2%) Mean 0.5%	0/50 (0%) SD 1%
Squamous Cell Papilloma Overall Incidence	Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 1/200 (0.5%)	Mean 0.5%	SD 1%
Squamous Cell Papilloma Overall Incidence #Stomach, Glandular:	Total	0/50 (0%)	,	,	Total	0/50 (0%)	, ,	, ,

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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Report Date: 08/04/2016

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC Male **Female** #Stomach, Glandular: Leiomyosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 1/200 (0.5%) Mean 0.5% SD 1% #Stomach, Glandular: Sarcoma (2%) 0/50 (0%)0/50 (0%)1/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total 0/200 (0%) SD 0% *Testes: Adenoma 6/50 (12%)3/50 2/50 (4%)0/50 (0%)**Overall Incidence** Total 11/200 (5.5%) Mean 5.5% SD 5% *Testes: Hemangiosarcoma 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1%

0/40

SD 0%

(0%)

0/46

0/48

0/191 (0%)

Total

(0%)

(0%)

0/49

(0%)

Mean 0%

0/48

SD 0%

(0%)

Total

0/41

0/48

0/176 (0%)

(0%)

(0%)

0/47

Mean 0%

(0%)

*Thymus: Sarcoma

Overall Incidence

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
*Thymus: Thymoma Benign								
		3/41 (7%) 3/48 (6%)	1/47 (2%)	1/40 (3%)		6/46 (13%) 8/48 (17%)	0/49 (0%)	5/48 (10%)
Overall Incidence	Total	8/176 (4.55%)	Mean 4.55%	SD 2.62%	Total	19/191 (9.95%)	Mean 10.03%	SD 7.16%
*Thymus: Thymoma: Benign, Malign	ant, NOS							
		3/41 (7%) 3/48 (6%)	1/47 (2%)	1/40 (3%)		6/46 (13%) 8/48 (17%)	0/49 (0%)	5/48 (10%)
Overall Incidence	Total	8/176 (4.55%)	Mean 4.55%	SD 2.62%	Total	19/191 (9.95%)	Mean 10.03%	SD 7.16%
*Thyroid Gland: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/199 (0.5%)	Mean 0.5%	SD 1%
*Thyroid Gland: C-Cell: Adenoma								
		5/50 (10%) 3/50 (6%)	6/50 (12%)	7/50 (14%)		4/50 (8%) 7/49 (14%)	2/50 (4%)	3/50 (6%)
Overall Incidence	Total	21/200 (10.5%)	Mean 10.5%	SD 3.42%	Total	16/199 (8.04%)	Mean 8.07%	SD 4.45%
*Thyroid Gland: C-Cell: Carcinoma								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 0/49 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	2/199 (1.01%)	Mean 1%	SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

on: Aug2016

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
*Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		6/50 (12%) 3/50 (6%)	6/50 (12%)	7/50 (14%)		5/50 (10%) 7/49 (14%)	3/50 (6%)	3/50 (6%)
Overall Incidence	Total	22/200 (11%)	Mean 11%	SD 3.46%	Total	18/199 (9.05%)	Mean 9.07%	SD 3.95%
*Thyroid Gland: Follicular Cell Adenoma								
		0/50 (0%) 0/50 (0%)	2/50 (4%)	1/50 (2%)		1/50 (2%) 0/49 (0%)	2/50 (4%)	1/50 (2%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	4/199 (2.01%)	Mean 2%	SD 1.63%
*Thyroid Gland: Follicular Cell Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 1/49 (2%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	3/199 (1.51%)	Mean 1.51%	SD 1.01%
*Thyroid Gland: Follicular Cell Carcinoma or Adenoma	:							
		0/50 (0%) 0/50 (0%)	2/50 (4%)	1/50 (2%)		2/50 (4%) 1/49 (2%)	2/50 (4%)	2/50 (4%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	7/199 (3.52%)	Mean 3.51%	SD 0.98%
*Urinary Bladder: Carcinoma or Papilloma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Version: Aug2016 Contract/Lab: All Laboratories

Species: RATS

Strain: Wistar-Han

Toxicology Data Management System

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Report Date: 08/04/2016

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
*Urinary Bladder: Papilloma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0% S	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Uterus: Adenoma								
						0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Uterus: Carcinoma								
						3/50 (6%) 1/50 (2%)	2/50 (4%)	1/50 (2%)
Overall Incidence					Total	7/200 (3.5%)	Mean 3.5%	SD 1.91%
#Uterus: Granular Cell Tumor B								
						0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Uterus: Hemangiosarcoma								
J						1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups **Route:** INHALATION

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Vehicle: AIR

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	Male			Female	
#Uterus: Leiomyosarcoma					
·			1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	1/200 (0.5%)	Mean 0.5%	SD 1%
tUterus: Malignant Mixed Mullerian Tumor					
			0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	0/200 (0%)	Mean 0%	SD 0%
#Uterus: Polyp Stromal					
			2/50 (4%) 6/50 (12%)	9/50 (18%)	5/50 (10%)
Overall Incidence		Total	22/200 (11%)	Mean 11%	SD 5.77%
Uterus: Sarcoma Stromal					
			1/50 (2%) 1/50 (2%)	1/50 (2%)	2/50 (4%)
Overall Incidence		Total	5/200 (2.5%)	Mean 2.5%	SD 1%
Uterus: Sarcoma Stromal or Polyp Stromal					
			3/50 (6%) 7/50 (14%)	10/50 (20%)	6/50 (12%)
Overall Incidence		Total	26/200 (13%)	Mean 13%	SD 5.77%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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	Male	Female	
#Uterus: Schwannoma Malignant			
		0/50 (0%) 1/50 (2%) 0/ 2/50 (4%)	(50 (0%)
Overall Incidence	Tota	,	D 1.91%
Uterus: Squamous Cell Papilloma			
		0/50 (0%) 0/50 (0%) 1/ 0/50 (0%)	(50 (2%)
Overall Incidence	Tota	l 1/200 (0.5%) Mean 0.5%	SD 1%
Vagina: Fibrosarcoma			
		0/50 (0%) 0/50 (0%) 0/ 1/50 (2%)	(50 (0%)
Overall Incidence	Tota		SD 1%
Vagina: Leiomyoma			
		0/50 (0%) 0/50 (0%) 0/ 0/50 (0%)	(50 (0%)
Overall Incidence	Tota	0/200 (0%) Mean 0%	SD 0%
Vagina: Polyp			
WL		0/50 (0%) 0/50 (0%) 0/ 0/50 (0%)	(50 (0%)
Overall Incidence	Tota		SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: Wistar-Han

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Zymbal's Gland: Carcinoma								
		0/50 (0%) 1/50 (2%)	0/50 (0%)	2/50 (4%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	0/200 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma or Adenoma								
		0/50 (0%) 1/50 (2%)	0/50 (0%)	2/50 (4%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied